

Appl. No. 09/871,318
Amdt. dated Sept. 2, 2003
Reply to Final Office Action of Nov. 5, 2002

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Cancel claims 1, 2 and 6-15 without prejudice or disclaimer.

Please amend claims 3 and 14. Please add new claims 20 to 37.

1. (Canceled) A transdermal formulation comprising a drug reservoir and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.

2. (Canceled) The transdermal formulation of claim 1, further comprising an effective amount of a drug permeation enhancer.

3. (Currently Amended) A transdermal formulation comprising an adhesive drug matrix reservoir and an effective amount of lasofoxifene ~~and~~ or a pharmaceutically acceptable ~~salts~~ salt thereof.

4. (Original) The transdermal formulation of claim 3, wherein the adhesive matrix is a solvent based pressure sensitive adhesive matrix.

5. (Original) The transdermal formulation of claim 3, wherein the adhesive matrix is a water based pressure sensitive adhesive matrix.

6. (Canceled) A transdermal formulation comprising a liquid reservoir drug reservoir and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.

7. (Canceled) A transdermal formulation comprising a free form hydroalcoholic gel and an effective amount of lasofoxifene and pharmaceutically acceptable salts thereof.

8. (Canceled) The transdermal formulation of any of claims 3 to 7, further comprising an effective amount of a drug permeation enhancer.

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9. (Canceled) The transdermal formulation of claim 8, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

10. (Canceled) The transdermal formulation of claim 9, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

11. (Canceled) The transdermal formulation of claim 8, wherein the drug permeation enhancer comprises an effective amount of a lower alkanol and an effective amount of glycerol monooleate.

12. (Canceled) The transdermal formulation of claim 11, wherein the effective amount of glycerol monooleate is about greater than or equal to 0.01 % w/w.

13. (Canceled) A transdermal device comprising a means for adhering the drug reservoir to the application situs and the pharmaceutical formulation of any of claims 3 to 7.

14. (Currently Amended) A device for administering an active agent to the skin or mucosa of an individual comprising a laminated composite of:

- a. a backing layer defining an upper portion of a reservoir and extending to the periphery of a peel seal disk;
- b. an active agent-permeable membrane extending to the periphery of the peel seal disk and the backing layer, and underlying the backing layer, the backing layer and membrane defining;
- c. the reservoir therebetween that contains ~~the formulation of claim 1~~ a transdermal formulation comprising an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof;
- d. the peel seal disc underlying an active agent-permeable membrane;
- e. a heat seal about the periphery of the peel seal disc, the active agent-permeable membrane and the backing layer;
- f. an adhesive overlay having a central portion overlying the backing layer and a peripheral portion that extends beyond the periphery of the peel seal disc; and
- g. a removable release liner underlying the peripheral portion of the adhesive overlay and the peel seal disc.

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15. (Canceled) A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical transdermal formulation of claim 1.

16. (Canceled) A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical formulation of claim 2.

17. (Currently Amended) A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with an effective pharmaceutical formulation of any of claims ~~3 to 7~~ 3 to 5.

18. (Original) A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with the device of claim 14.

19. (Original) A method for treating or preventing a disorder associated with estrogen deficiency in a subject comprising contacting a dermal situs of the subject with the device of claim 14.

20. (New) The transdermal formulation of any one of claims 3 to 5, further comprising an effective amount of a drug permeation enhancer.

21. (New) The transdermal formulation of claim 20, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

21. (New) The transdermal formulation of claim 21, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

22. (New) The method of claim 17, wherein the pharmaceutical formulation further comprises a drug permeation enhancer.

23. (New) The method of claim 22, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

24. (New) The method of claim 23, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

25. (New) The device of 14, wherein the pharmaceutical formulation further comprises a drug permeation enhancer.

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26. (New) The device of claim 25, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

27. (New) The device of claim 26, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

28. (New) A transdermal device comprising a means for adhering a drug reservoir to the application situs and the transdermal formulation of any of claims 3 to 5.

29. (New) The transdermal device of claim 28, wherein the transdermal formulation further comprises an effective amount of a drug permeation enhancer.

30. (New) The device of claim 29, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

31. (New) The device of claim 30, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

32. (New) A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with a transdermal formulation comprising a free from hydroalcoholic gel and an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof.

33. (New) The method of claim 32, further comprising an effective amount of a drug permeation enhancer.

34. (New) The method of claim 33, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

35. (New) The method of claim 34, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.

36. (New) A method for treating or preventing a disorder associated with estrogen deficiency or dysregulation in a subject comprising contacting an application situs of the subject with a transdermal formulation comprising a liquid reservoir drug formulation comprising an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof.

37. (New) The method of claim 36, further comprising an effective amount of a drug permeation enhancer.

38. (New) The method of claim 37, wherein the drug permeation enhancer is an effective amount of cell-envelope disordering compound.

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39. (New) The method of claim 38, wherein the cell-envelope disordering compound comprises an effective amount of a lower alkanol.